



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

JAN 9 1997

0782 '97 DEC 16 P1:39

Mr. Ian Hicks  
President  
Pershing Products  
17991 Fitch  
Irvine, California 92614

Dear Mr. Hicks:

This is in response to your letter of October 8, 1996 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement on the label of your product, LDL-Lite:

Reduce Your Cholesterol up to 15% in 4 weeks.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to prevent, treat, or mitigate heart disease, in that it claims that it will "reduce your cholesterol up to 15% in 4 weeks." This impression is reinforced by the use of a heart symbol.

A product that claims to reduce cholesterol, but is not used in the context of dietary management, is a drug within the meaning of section 201(g)(1)(B) of the act, and is subject to regulation under the drug provisions of the act. If you intend to make a claim of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

James Tanner, Ph.D.  
Acting Director,  
Division of Programs and  
Enforcement Policy  
Office of Special Nutritionals  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Los Angeles District Office, Office of Compliance, HFR-PA200  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

**PERSHING**

RECEIVED BY THE R O D U C T S  
OFFICE OF SPECIAL  
NUTRITIONALS. HFS-450

8 October 1996

'96 OCT 22 P3:48

John Gordon  
Acting Director  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals (HFS-456)  
Center for Food and Safety and Applied Nutrition  
Food and Drug Administration  
200C Street, S.W.  
Washington, DC 20204

0783 '97 DEC 16 P1:39

**NOTIFICATION OF STATEMENT OF NUTRITIONAL SUPPORT**

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343 @ (6), this is to notify the FDA that this company intends to include the following statement in the labeling of its LDL Lite product:

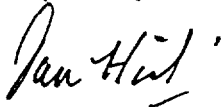
Reduce Your Cholesterol up to 15% in 4 Weeks.

Independent clinical studies have indicated that Beta Sitosterol and Pectin, in conjunction with a caloric intake program, have been shown to reduce serum LDL cholesterol levels by up to 15%.

This statement is based on substantiation and as such is truthful and not misleading. The statement will be accompanied by the required disclaimer indicating that the claim has not been evaluated by FDA and that the product is not intended to diagnose, treat, cure or prevent any disease.

A copy of the proposed product label is attached hereto..

Respectfully submitted,



Ian Hicks  
President

49365

NUTRITION FACTS	
Serving Size 1 Tablet	
Servings Per Container 48	
Amount Per Tablet	% Daily
Beta-Sitosterol 300mg	-
Pectin 30mg	-
*Daily Value Not Established	

Suggested Use: One tablet with a full glass (at least 8 ounces) of water or other liquid 30 minutes before each of 3 meals. No more than 6 tablets per day.

Independent clinical studies have shown that the use of beta-sitosterol-pectin complex tablets adjusts cholesterol to more normal levels by reducing dietary fat and cholesterol absorption from the foods we eat.\*\*

\*\* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

LDL-Ute supplements DO NOT CONTAIN artificial coloring, artificial flavors, sugar, preservatives, petroleum based products, dyes, yeast, wheat or corn flour, starch, or milk products.

**Reduce  
Your Cholesterol  
UP TO 15% in 4  
Weeks!\***

**LDL-Ute™**

48 Tablets Food Supplement

 National Cholesterol Education Program  
INFORMATION ENCLOSED

**CAUTION:** Please consult your health care practitioner before starting any nutritional modification program or if you have a disease or health related program requiring lowering your cholesterol levels. Not recommended for pregnant or lactating women. Keep out of reach of children. If safety seal is broken or missing, do not use.

\*Independent Clinical studies have indicated that Beta-Sitosterol and Pectin, in conjunction with a caloric intake program, have been shown to reduce serum LDL Cholesterol levels by up to 15%. Pershing Products, Inc., Irvine, CA. *Beta-Sitosterol-Pectin Complex*, January 1996. The National Institute of Health states that for those with high blood cholesterol, lowering your cholesterol level can reduce your risk of a heart attack.

Questions or Comments? Please call 1-800-854-8353, 10 A.M. to 4 P.M. C.S.T., Monday thru Friday.



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